

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST IN BIOMEDICAL PUBLICATIONS IN VIEW OF THE INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS RECOMMENDATIONS

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Abstract

As potential conflicts of interest (COI) are common in biomedical research, handling related issues and managing disclosures is increasingly important. The International Committee of Medical Journal Editors (ICMJE) revised its guidance on COI in 2019 and introduced the latest version of the COI Disclosure Form in 2021. These documents provide guidance regarding COI policy for ICMJE member and non-member journals. The 2019 revision overviews the main changes in the ICMJE policy. The ICMJE prioritizes appropriate COI disclosures by authors and all others involved in scholarly publishing. Increasing the global awareness of the COI updated policies among all stakeholders is essential for strengthening ethical standing of journals.

Keywords: Conflict of Interest, Publishing, Editorial Policies, Scientific Societies, Periodicals as Topic

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INTRODUCTION

Managing potential conflicts of interest (COI) continues to be challenging in biomedical journals. As the credibility of scholarly research depends on unbiased and transparent writing, peer review, and editorial decisions, all of which can be affected greatly by COI, and since COI can arise at all stages of research and publishing [1], the integrity of scientific communication relies heavily on COI disclosure.

Since the early 2000s, the International Committee of Medical Journal Editors (ICMJE) has prioritized potential

COI disclosures for individual authors and all those involved in the peer review and scholarly publishing. The ICMJE stated that “public trust in the peer review process and the credibility of published articles depend in part on how well COI is handled” [2]. Nonetheless, problems with COI disclosure have persisted due to the difficulties surrounding the COI handling, or transparency, as the interpretations of potential COI depend on individual beliefs and perceptions with non-disclosure, incomplete, and inconsistent disclosures frequently encountered by editors [3].

To facilitate proper handling of COI, the ICMJE introduced a uniform disclosure form in 2010 [4]. Important issues, however, remained. For example, the ICMJE recognized that the term “potential conflict of interest” was confusing to authors and readers, and that it led to misunderstandings, misapplications, and misinterpretations of COI disclosures [3, 5]. To address such issues, the ICMJE updated its guidance in 2019, and introduced the revised COI disclosure form in 2021 [6, 7].

ICMJE REVISED STATEMENTS

Compared with the 2008 edition [8], the ICMJE Recommendations were substantially amended in 2013, especially in parts concerning authorship and COI. Authorship criteria included a fourth criterion requiring all co-authors to be accountable for all aspects of their work to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved [9]. Furthermore, COI was now listed under the subheading “Author Responsibilities”, and the concept that “perceptions of COI” are as important as actual COI was introduced [9]. Even when there is no COI, readers may think that there is a conflict. Like actual, the perceived COI might be risky and detrimental to the public trust [10].

To enforce accurate COI disclosures, it is necessary to comprehensively and understandably define what is COI. The 2013 edition of the ICMJE Recommendations provides a succinct, clear, and detailed explanation of COI [9].

In 2018, the ICMJE revised its Recommendations by adding the statement that “purposeful failure to disclose COI is a form of misconduct” [11]. In the section on Publishing and Editorial Issues Related to Publication in Medical Journals, it was highlighted that scientific misconduct includes purposeful failure to disclose COI, and, in situations where there are concerns regarding such misconduct, an expression of concern may be published [11].

Until the latest revision of the ICMJE Recommendations in 2019, journals had often published corrections in cases of COI non-disclosure. However, the ICMJE now stresses that simply adding a previously missing disclosure of potential COI is insufficient. This is a move that makes it easier for journals and institutions to sanction authors who conceal potential COI [12].

The latest edition of the ICMJE Recommendations introduced several significant changes. One notable

change is that the term “relationships and activities” is used along with “COI” to improve the understanding of conflicts. Authors should disclose all activities or relationships, whether financial, non-financial, personal, or institutional, that “are related to the content” of a submission. The document now stresses the importance of readers who may determine whether such “relationships and activities” have an influence on research output. Accordingly, authors should demonstrate their commitment to transparency through complete disclosure to ensure the trustworthiness of the scientific process [6]. The way things appear to readers is as important as how they actually are. With this change, final decisions about what is and what is not a potential COI no longer rest with authors. Readers are now entrusted with the responsibility to evaluate author disclosures of relationships and activities. Until now, authors themselves have been responsible to disclose what they perceived potentially conflicting [13]. The latest ICMJE Recommendations have encouraged all those involved in the editorial process to transparently disclose COI.

DISCLOSURE FORM CHANGES

The ICMJE first introduced its COI disclosure form in 2010, aiming to implement a uniform tool for disclosing financial and non-financial interests. This form was made publicly available on the ICMJE website. At that time, the feedback regarding non-financial COI disclosures was negative [14]. Specifically, there was concern about the “immense difficulty in defining COI beyond those that involve the direct exchange of money.” This led the ICMJE to remove direct questions about non-financial COI, as well as questions related to COI of authors’ spouses and minor children [14].

Since the consequences of non-financial COI or other circumstances that may influence research are significant, the ICMJE decided to reword questions about non-financial conflicts and introduced points about any “relationships or activities” that could be perceived to influence scholarly work [14].

In 2020, ten years after publicizing its first uniform COI disclosure form, the ICMJE made significant changes to straighten the disclosure, and the new Disclosure Form was introduced in February 2021. The new form begins with the clause “in the interest of transparency” and specifically states that all relationships, activities, and interests that may affect the content of the submitted work need to be disclosed to demonstrate the author’s commitment to transparency [7]. In the instructions on how to use the Disclosure Form, considerable attention

is paid to the importance of transparency in scientific publications.

IMPLICATIONS OF NON-DISCLOSURE

As a matter of professional ethics, authors are expected to disclose potential COI and anything that might result in bias. All stakeholders should understand that numerous financial and non-financial (personal) conflicts accumulate over an individual's academic career. They should also admit that COI, particularly those not obvious for readers, may have negative consequences if not properly managed [15]. Disclosed and undisclosed COI may affect the reliability of clinical evidence while the introduced biases may diminish the value of scientific research [16].

The ICMJE emphasizes that COI may also affect editorial decisions, urging responsible editors with potential COI to hand over their duties to peers. Editors control priority of articles in their journals. They ensure the journal integrity by enforcing authors' adherence to the instructions, but their own interests and biased actions are difficult to manage [17]. The peer review process and editorial decisions may be influenced by a variety of conflicting financial and non-financial relationships which most of the time remain obscure [17].

PERSPECTIVES

Managing COI is increasingly difficult due to the expanding relationships between researchers and sponsoring organizations. Such relationships are likely to become more complex and challenging in the future [3]. What can be done to appropriately manage COI and promote transparency in the scholarly publishing?

While there have been suggestions to create a central database of author COI and integrate it with journals and

publishers, such a move may incur additional maintenance tasks and related financial expenses [3, 16].

Journal editors are encouraged to enforce the ICMJE guidelines, to conform to the Committee on Publication Ethics (COPE) statements, and to maintain the integrity of all editorial processes [18, 19]. However, COI disclosure policies are still implemented with difficulties. Some even argue that simply disclosing potential COI is insufficient [20] since the disclosure itself does not remove, negate, or prevent biases [16, 20].

The revised ICMJE Disclosure Form helps authors, reviewers, and editors to better understand what constitute COI and how to disclose all potential conflicts. Increasing the global awareness of the advantages of the new form is warranted to update related policies and ensure the integrity of the scholarly publishing. Authors may lack knowledge and skills for disclosing potential COI. They should be instructed to fill out the form and advised to avoid non-disclosure. The awareness of authors and other stakeholders of updates in ethical publishing [21, 22] may further increase their adherence to COI policies and management.

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CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

DISCLAIMER

No part of the review was copied from or published elsewhere.

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ХАЛЫҚАРАЛЫҚ МЕДИЦИНАЛЫҚ ЖУРНАЛДЫҚ РЕДАКЦИЯЛАРДЫҢ ХАЛЫҚАРАЛЫҚ КОМИТЕТІНІҢ ҰСЫНЫСТАРЫНА БИОМЕДИЦИНАЛЫҚ ЖАРИЯЛАНДЫРУДАҒЫ ҚЫЗЫҚУШЫЛЫҚТАРДЫҢ АШУЫ

Түйіндеме

Биомедициналық зерттеулерде ықтимал мүдделер қақтығысы (ЫМҚ) жиі кездесетіндіктен, мүдделер қақтығысы туралы ақпаратты ашып көрсетуімен байланысты мәселелерді шешу өзекті мәселе болып табылады. 2019 жылы медициналық журналдар редакторларының халықаралық комитеті (ICMJE) ғылыми жұмыс нәтижелерін жүргізу, сипаттау, редакциялау және медициналық журналдарда жариялау туралы ұсынымдарын қайта қарастырып, 2021 жылы ықтимал мүдделер қақтығысы туралы ақпараттың (PCP) соңғы нұсқасын ұсынды. Бұл құжаттарда ICMJE құрамына кіретін журналдарға, сондай-ақ қалған жарияланымдарға да арналған ЫМҚ саясаты бойынша ұсынымдары бар. ICMJE авторлар және ғылыми жарияланымдарды жазуға қатысы бар барлық тұлғалардың ЫМҚ-ны ашып көрсетуіне басымдық береді. Барлық мүдделі тараптар арасында ЫМҚ-ның жаңартылған саясаты туралы жаһандық хабардарлығын арттыру журналдардың этикалық мәртебесін нығайту үшін өте маңызды болып табылады.

Түйінді сөздер: Мүдделер қақтығысы, баспа ісі, редакциялық саясат, ғылыми қоғамдар, мерзімді басылымдар тақырып ретінде

Дәйексөз үшін: Т. Кодзима. Халықаралық медициналық журналдық редакциялардың халықаралық комитетінің ұсыныстарына биомедициналық жарияландырудағы қызықушылықтардың ашуы. Медициналық гипотеза мен этиканың Орта Азиялық журналы. 2021; 2 (1): 18-22. <https://doi.org/10.47316/cajmhe.2021.2.1.03>

РАСКРЫТИЕ ПОТЕНЦИАЛЬНЫХ КОНФЛИКТОВ ИНТЕРЕСОВ В БИОМЕДИЦИНСКИХ ПУБЛИКАЦИЯХ В СООТВЕТСТВИИ С РЕКОМЕНДАЦИЯМИ МЕЖДУНАРОДНОГО КОМИТЕТА РЕДАКТОРОВ МЕДИЦИНСКИХ ЖУРНАЛОВ

Резюме

Поскольку потенциальные конфликты интересов (COI) являются обычным явлением в биомедицинских исследованиях, решение проблем, связанных с раскрытием информации о конфликтах интересов, является актуальным вопросом. Международный комитет редакторов медицинских журналов (ICMJE) в 2019 году пересмотрел свои рекомендации по проведению, описанию, редактированию и публикации результатов научной работы в медицинских журналах и представил последнюю версию формы раскрытия потенциального конфликта интересов (ПКИ) в 2021 году. Эти документы содержат рекомендации относительно политики ПКИ для журналов, которые входят в ICMJE, а также для остальных изданий. ICMJE уделяет приоритетное внимание раскрытию ПКИ авторами и всеми другими лицами, участвующими в написании научных публикаций. Повышение глобальной осведомленности об обновленной политике ПКИ среди всех заинтересованных сторон имеет важное значение для укрепления этического статуса журналов.

Ключевые слова: Конфликт интересов, издательское дело, редакционная политика, научные общества, периодические издания как тема

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